DEPARTMENT OF RESEARCH PROGRAMS
Walter Reed National Military Medical Center

Military Medical Research News

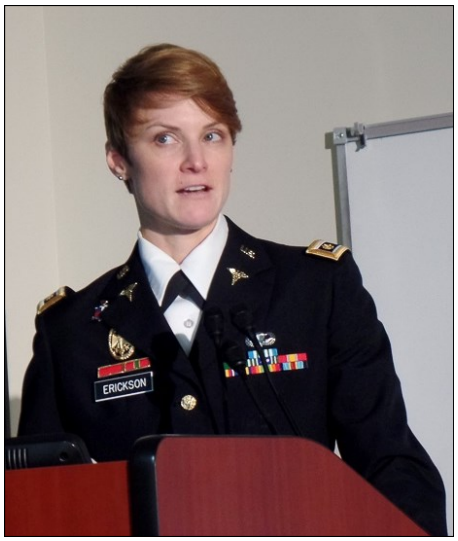
Vol. 4, Issue 11 ▪ November 2017

Research fuels advances in breast cancer care
First-time summit highlights progress, remaining challenges

by Paula Amann

The power of research to shape patient care and the power of illness to reshape a woman's life were themes of a Breast Cancer Summit hosted by the John P. Murtha Cancer Center on Oct. 19. The inaugural half-day event at Walter Reed National Military Medical Center drew more than 90 people.

Breast cancer is a "biographical disruption," stressed Army Maj. (Dr.) Delnora Erickson, the associate program director of the radiation oncology residency at Walter Reed. It can have repercussions for a patient's career and relationships, on top of the physical effects of the disease and its treatment, Erickson explained, citing a 2015 study by Fenlon et al.



At the Breast Cancer Summit Oct. 19, Army Maj. (Dr.) Delnora Erickson, the associate program director of the radiation oncology residency at Walter Reed Bethesda, surveys the state of "survivorship" among patients who have undergone radiation therapy . The John P. Murtha Cancer Center hosted the event. (Photos by Paula Amann)

Overall, there's good news and bad news on the breast cancer front, noted keynote speaker Stanley Lipkowitz of the National Cancer Institute.

Incidence in the United States has climbed since 1970 from some 68,000 to 252,700 projected new cases in 2017, the institute documents.

However, the relative number of deaths has fallen markedly over the same period, said Lipkowitz, the chief and senior investigator of the Women's Malignancies Branch of the institute's Center for Cancer Research.

At the Breast Cancer Summit, Air Force Lt. Col. (Dr.) Peter Learn, a surgical oncologist at the Murtha Cancer Center, advocates "less is more" in surgery for the disease. Learn is associate chair of surgery for quality and patient outcomes in the Uniformed Services University–Walter Reed Department of Surgery.

Researchers are learning about the varied molecular makeup of breast cancer, Lipkowitz noted. Some 70 percent of breast cancers are linked to estrogen or progesterone (ER/PR) receptors, human epidermal growth factor receptor 2 while 20 percent are associated with an excess of human epidermal growth factor receptor 2 (HER-2). Another 20 percent have neither marker.

"These are telling us breast cancer is much more complicated than we know," said Lipkowitz.

His institute has been running clinical trials on the tumor necrosis-factor apoptosis-inducing ligand (TRAIL). TRAIL is a cell protein produced in most human tissues, which can cause apoptosis, or cell death, by attaching to cancer cells.

See ADVANCES, page 6

Department of Research Programs

Army Col. Peter Weina, chief of Department of Research Programs (official photo)

The Department of Research Programs at Walter Reed National Military Medical Center supports research in the National Capital Region.

This monthly newsletter covers events, research and administrative policies and procedures, research studies and collaborations, department operations, workshops and other programs across our region.

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This newsletter appears monthly. We welcome your story ideas, comments, corrections and photographs (action shots preferred). ***Please email material by the 15th day of the prior month for the following month's issue to paula.m.amann.ctr@mail.mil.*** Not on our email list? Please drop us an email, and we would be glad to add your name.

Research First Steps

Our research protocol analysts are here to help you start the project and your submission. To make an appointment with a protocol analyst, please call the Department of Research Programs at 301-295-8239. We are located in Building 17B, Suite 3C, on the third floor near the elevators.

Research Roundtable Schedule

Walter Reed Bethesda, America Building (Building 19), Room 2301

- Tuesday, Nov. 21, 1200-1300
  Sanjur Brooks, How to Craft a Data-Sharing Agreement
- Tuesday, Dec. 19, 1200-1300
  Vicki Miskovsky: Advertisements for Research

Disclaimer

The views expressed in this newsletter are those of the authors and do not reflect the official policy of the Department of Army, Navy, Air Force, Department of Defense or U.S. government. The identification of specific products, scientific instrumentation, or organization is considered an integral part of the scientific endeavor and does not constitute endorsement or implied endorsement on the part of the author, DoD, or any component agency.

EIRB Tips of the Month

Tout your team members

Be sure to list your key personnel (e.g., associate investigators), those with and without access to the Electronic Institutional Review Board (EIRB), in your EIRB protocol application. Key personnel who do not have EIRB access should be listed in section 8.1 of the EIRB Protocol Application.

You can add and delete the Protocol Contacts (email-only access) and the Department Heads (read-only access) without an IRB submission. Head for the Study Management tab and select Key Personnel to add users for these roles only.

To add new principal investigators, associate investigators and research support staff that have read-and-write access, you must submit a Modification Submission form via EIRB for IRB review and approval.

Take advantage of training

Consider attending the bimonthly EIRB Q & A sessions (see schedule on page 11). Or register for the monthly EIRB Refresher Webinars, which you can conveniently view at your desk. Finally, check intranet banners for our department and Walter Reed Bethesda to find upcoming sessions of Lunch & Learn: Research 2.0, Research Roundtable, and other training.

— compiled by Wendy Gilbert, Institutional Review Board manager

CHIEF'S CORNER

Promoting research is at the heart of our mission

The Department of Research Programs has a dual mission. By regulatory mandate, we spend 50.5 percent of our time and effort on protection of human subjects, yet we are not a policing organization. Our staff is also here to serve you in your research endeavors.

We are committed to spending 49.5 percent of our time and effort encouraging research here at Walter Reed Bethesda. It actually turns out to be so much more because when we engage with you, we both encourage research and protect human subjects.

Army Col. Peter J. Weina (Archival photo by John Fadoju)

We have many resources to assist you in your research. This department specifically generates funds for Graduate Medical Education (GME) and provides hundreds of thousands of dollars for GME research every year. We have grants managers, technology transfer specialists, logisticians, statisticians and protocol development specialists, who are here to help you in executing your research.

While websites, handouts and seminars can also help, nothing can replace the face-to-face meeting for getting your questions answered, so you can start your study. Our staff is largely located in Suite 3C of Building 17B, on the third floor, two stories above the gym.

The suite is an 8 to 10-minute walk from anywhere in the hospital. My office is by the front door and if the door is open, please come in, talk, and let me know personally how we can serve you best.

You have my personal promise that our staff members will take the time to talk with you and answer your questions. Please come see us and give us an opportunity to assist you.

Col. Peter J. Weina
Director, Department of Research Programs

GETTING STARTED WITH THE INSTITUTIONAL REVIEW BOARD AT WALTER REED BETHESDA

A convened IRB panel meets twice a month, with actions assigned based on submission deadlines.

Submission deadlines are the dates that the IRB receives a submission with all administrative, scientific and any other required pre-reviews *already done. Please work with a research protocol specialist and refine your project in time to make these deadlines.*

Expedited actions have no submission deadlines, because the IRB reviews them independently of the convened meeting schedule.

However, please follow these deadlines to help build our IRB agenda for the rest of 2017. Thank you for your cooperation.

Convened IRB Meetings	Submission Deadlines (Time: 1600)
November 9	October 26
November 16	November 2
December 14	November 24
December 21	December 7

ANNOUNCEMENTS

Series spotlights data-sharing agreements, quality improvement

Please put Lunch and Learn: Research 2.0 on your calendar for noon to 1 p.m. on the second and fourth Wednesdays, in Room 1369 of Building 8. On Nov. 8, Army Col. Ann Nayback-Beebe, deputy chief of the Department of Research Programs, will parse quality improvement, performance improvement, evidence-based practice and research.

Two weeks later, on Nov. 29, the series resumes with a webinar from Public Responsibility in Medicine and Research on "Electronic Informed Consent: Ethical, Regulatory, and Practical Considerations." Participants can earn credits for the Minimum Education Requirements Framework (MERF) and continuing education for this session.

In the interim, on Tuesday, Nov. 21, the program manager for Human Research Protections, Sanjur Brooks, will speak at the Research Roundtable in Desert Conference Room 2301 of building 19. Her topic, "How to Craft a Data-Sharing Agreement," will be relevant to any research team that collaborates with outside partners.

Website changes aimed at easing access for researchers

The Department of Research Programs is striving to make its intranet website work better for you. Go to Education, Training and Research, then click on the green puzzle piece labeled Research to reach the color-coded pyramid on the department's home page. The clickable "bricks" will take you on a tour of department services.

Many of our teams have new, streamlined landing pages. Some have new tabs to help you locate needed forms, templates and training. If you have constructive ideas about how to further improve the department's web presence, please contact John Fadoju via john.o.fadoju.ctr@mail.mil.

Packets for Research & Innovation Month contests coming soon

The Research Education Services team is laying the groundwork for six different competitions in research and inquiry that will culminate next May. Look for a release of competition materials on Monday, Nov. 20. ⊡

Interested in data analysis?

Let the biostatistics team at the Department of Research Programs help.
With two weeks' notice, we can lecture on many topics for you and five or more people:

- *Introduction to statistics (including types of variables, hypothesis testing)*
- *Sample size estimation*
- *Multiple comparisons between groups*
- *Confidence intervals*
- *Randomized clinical trials – the Consolidated Standards of Reporting Trials (CONSORT) checklist*
- *Clinical research design (including retrospective, prospective and case control)*
- *Diagnostic tests for sensitivity and specificity*
- *Estimating reliability between raters*
- *Odds ratios and relative risks*
- *Regression analysis*
- *Principal component analysis and factor analysis*
- *Introduction to Statistical Package for Social Sciences (SPSS)*
- *Analyzing with Excel (including pivot tables, row and column calculations, and graphing)*
- *New this year: Introduction to R (a statistical programming language)*

Got questions? Suggestions? Ready to schedule a class?
Contact Francois Tuamokumo, Ph.D., at francois.tuamokumo.civ@mail.mil

Town Hall provides forum for research community

by Paula Amann

Capt. John Eckert, director, Human Research Protection Program, Office of the Assistant Secretary of Defense for Health Affairs & the Defense Health Agency, headed a panel of colleagues from DHA fielding questions and concerns from researchers and related staff on Oct. 26. The 95-minute session drew some 40 people.

The greatest number of questions revolved around the Electronic Institutional Review Board. A couple of people raised concerns about the responsiveness of the help desk.

One technically-minded attendee urged getting access to the raw data within the system, before any potential transition to another system. In answer to another question, Eckert affirmed that the steering committee that oversees EIRB does include people who use the system.

Attendees raised a wide range of other topics, which Eckert and his team also addressed:

- How do you enroll small numbers of non-service members to round out the participant pool of research project in military medicine? It takes a "Secretarial Designation" to get such a waiver, and DHA can help.
- Is there an office within DHA that consolidates medical research data? Eckert mentioned the Solutions Delivery System, or J6, within the agency, which is planning for a "data lake" to do just that.
- What kind of training does the staff of the Department of Research Programs receive? All staff members do role-based training through the Collaborative Institutional Training Initiative. In addition, they will start new training for the Health Insurance Portability and Accountability Act (HIPAA) this month.
- How should researchers balance regulations by the DHA and by the individual services (i.e., Army, Navy, Air Force and Marines)? The DHA will oversee regulations at military treatment facilities by Oct. 1, 2018.

"We're not there yet, but we're working toward that harmonization," Eckert said.

- Why do we need data-sharing agreements? These protect privacy and confidentiality of patient data.

U.S. Public Health Service Capt. John Eckert, the director of the Human Research Program at the Defense Health Agency, emcees the Research Town Hall on Oct. 26. (Photo by John Fadoju)

- When can researchers expect new guidance on the revised Common Rule governing human subjects research? Release of the revised Common Rule is set for January 2019, Eckert said. More detailed guidance will follow, perhaps first from the U.S. Department of Health and Human Services.
- What is the reason for letters of support in multisite studies? These serve as endorsement letters, affirming that the research team is suitably qualified for the study at hand, said Deborah Kessler, a veteran protocol analyst.
- Can the Institutional Review Board serve as a privacy board? It can, and DHA has developed a process for that role.

"It may not seem like a big thing, but it shaved weeks off the review process," said Rita DeShields, the data sharing compliance manager at DHA. ⊡

ADVANCES, from page 1

As for established treatments, research shows that radiation lowers the risk of recurrence, boosts rates of breast preservation and helps patients live longer, said Erickson.

Yet, breast cancer survivors often cope with side effects ranging from acute fatigue to long-term effects such as increased risk of cardiac disease and cardiac mortality, in proportion to the amount of radiation directed at the heart, Erickson noted. She recommended the technique of a deep-breath hold during radiation to push the heart away from the radiation site.

On another treatment front, Air Force Lt. Col. (Dr.) Peter Learn traced the history of surgery and research from the late 1800s to today. Early surgeons believed in radical mastectomy, removing as much of the breast and surrounding tissue as possible, recounted Learn, a surgical oncologist with the Murtha Cancer Center.

Stanley Lipkowitz, chief and senior investigator of the Women's Malignancies Branch of the Center for Cancer Research at the National Cancer Institute, presents the latest research on breast cancer. Lipkowitz was the keynote speaker at the Breast Cancer Summit Oct. 19. His current research includes clinical trials on the use of tumor necrosis-factor apoptosis-inducing ligand (TRAIL) to kill cancer cells. (Photo by Paula Amann)

Over the decades, research has moved the field to the more limited lumpectomy and to a more cautious approach to axillary surgery, or the removal of lymph nodes in the armpit, Learn said.

"Less is more," Learn stressed.

He noted that without axillary surgery, patients have fewer complications and equivalent survival rates.

In contrast, extensive surgery is linked to lymphedema, swelling of the limbs due to the buildup of lymph fluid, noted physical therapist Ellen Levy. The associate director of scientific technologies at the Breast Care Center of the Murtha Cancer Center, Levy signaled the importance of detecting and treating lymphedema, which can limit basic movement such as lifting the arm.

Lymphedema is "a chronic condition, but it's not static," Levy said. "It can progress."

Beyond diagnosis and treatment, breast cancer survivors can play a role in staying healthy. Although some of the data conflict, Erickson cited studies linking alcohol consumption of as little as a half glass of wine daily with breast cancer. She urges patients to stop drinking alcohol, except for special occasions.

Other research, Erickson said, suggests that mortality of all kinds is higher among breast cancer survivors who are current smokers than survivors who have never smoked.

Putting a face on breast cancer was a survivor, Navy Capt. Ann Monasky, who chairs the Oral Diagnosis Department at the Navy Postgraduate Dental School.

Besides radiation and chemotherapy, Monasky noted the importance of having a supportive web of friends and family. She also mentioned a sense of humor and hope as keys to survival.

"Back is something you don't want to go to," Monasky said. "You have to keep going forward."

Monasky returned to work, gave up her motorcycle and got a puppy, all with the goal of "finding my normal," a good yet different life than she had before her cancer.

In their diversity, the summit's speakers reflected the range of providers involved in treating breast cancer, from surgeons, radiation oncologists and pathologists to physical therapists.

"It does really take a team," said Army Col. (Dr.) Jeremy Perkins, a medical oncologist who serves as deputy director of the Murtha Cancer Center. "The integration of those players does really make the sum greater than its parts." ⊡

Technology transfer made plain at Lunch and Learn

by Paula Amann

When the last Ebola outbreak hit West Africa in 2014, the United States was poised to help. This readiness stemmed in part from work by the U.S. Army Medical Research Institute of Infectious Diseases to create countermeasures for the often-fatal viral disease. The institute licensed the antibody in its therapeutic cocktail to a pharmaceutical company, which could produce and distribute it.

Martin Hindel, research attorney with the Business Office of the Department of Research Programs cited this real-world example in his talk, "Introduction to Technology Transfer," on Oct. 25, part of the twice-monthly series, Lunch and Learn: Research 2.0. The event drew 32 people, many of whom stayed after the official close of the noontime program to pepper Hindel with questions.

The Ebola antibody fits the legal definition of technology, Hindel explained. In practical terms, it can range from a prosthetic arm to a drug and even an algorithm for data analysis.

Technology transfer occurs when a "federal laboratory" moves its technology to a partner outside the government, which in turn moves the technology toward the marketplace.

Martin Hindel, research attorney with the Department of Research Programs, unpacks the fine points of technology transfer at a Lunch and Learn Oct. 25. (Photo by John Fadoju)

Technology transfer grew out of a U.S. economic downturn in the mid-1970s and congressional inquiry that showed federally backed innovation was returning little to the economy. In response, Congress passed laws in 1980 and 1986 to foster the movement of new technology from federal laboratories to the outside world.

Achieving that exchange usually requires a cooperative research and development agreement (CRADA). This kind of "glorified contract," Hindel said, permits the federal laboratory to allocate to any partner to the agreement staff, facilities, resources, and most importantly, intellectual property rights, but not funds.

"It's a faster, more flexible and better model for technology transfer" than the procurement process, Hindel said.

Even before crafting a CRADA, researchers may need a nondisclosure agreement to protect their idea. Hindel urged contacting the Business Office before sharing an innovation with a potential partner.

"We will help you get a nondisclosure agreement in place to protect you and the government's interest," Hindel said.

Researchers sometimes rely on a memorandum of understanding between different federal entities to protect their ideas, but this legal tool comes with its own drawbacks. The MOU lacks data protection, does not allocate resources and provides no confidentiality, cautioned Hindel.

To sort out the legal options, Hindel suggested that researchers contact the Business Office of the Department of Research Program, which has its own landing page on the intranet, replete with contact numbers.

"We can't start the conversation," Hindel said. "We're relying on you."

To learn more about technology transfer, find slides for the talk at this link.

Unpacking pragmatic clinical trials: ethics, regulations

Once researchers have shown a medication curbs a given disease, it may be time to run a pragmatic clinical trial. This type of trial attempts to answer questions that clinicians and patients want to know, such as the comparative effectiveness of different treatments in different populations, along with their benefits and drawbacks.

Pragmatic trials can raise their own set of ethical and regulatory questions. To explore them, the Department of Research Programs hosted "Studying Effectiveness: Ethical and Regulatory Considerations in Pragmatic Clinical Trials," a webinar from Public Responsibility in Medicine and Research (PRIM&R), on Oct. 11.

Leading the training were Dr. P. Pearl O'Rourke, director of human research affairs with a private consulting firm and associate professor of pediatrics at Harvard Medical School, and Dr. Jeremy Sugarman, Harvey M. Meyerhoff professor of bioethics and medicine at the Berman Institute of Bioethics at Johns Hopkins University.

From left, Donald Miller, research assistant for obstetrics and gynecology; Kathleen Noel, research coordinator for radiation oncology; and Virginia Schmidt, research coordinator for hematology/oncology take in the webinar on Oct. 11 (Photo by Paula Amann)

Ethical issues under scrutiny during the webinar ranged from data access by the research team to data security on cell phone apps. Presenters also shared alternatives to the traditional consent form, ranging from a waiver to an opt-in or opt-out approach.

To learn more, find the webinar and accompanying slides at this link.

TRAINING FOR RESEARCHERS

Ready for research? The Department of Research Programs has the right training for your role. We offer workshops for researchers working with human subjects:

- Collaborative Institutional Training Initiative (CITI)
- Minimum Educational Requirement Framework (MERF)

Arrange training for your department or join our monthly classes. We have only eight spaces per class, so sign up now!

Your Monthly Class

Find it in Building 5), fourth floor, Computer Classroom 1 (Room 4010).

- Nov. 14, 2-3 p.m.
- Dec. 12, 2-3 p.m.

Questions? Please contact Ms. Lisa Thompson, supervisory research education specialist, at 301-295-8231 or lisa.p.thompson5.civ@mail.mil.

You belong in the CITI. Start training today!

RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson

Lisa Thompson, academic research education specialist (Photo by subject)

The Department of Research Programs (DRP) invites you to the Research Roundtable on the third Tuesday of most months. Our new program includes a 15-minute presentation on a "how to" research topic, followed by 45 minutes of questions and answers about challenges with conducting research, navigating the Electronic Institutional Review Board or submitting actions to the Institutional Review Board.

At the next roundtable on Nov. 21, **Sanjur Brooks**, the program manager for Human Research Protections, will speak on the topic, **"How to Craft a Data-Sharing Agreement."** We invite you to present as well. If there is a pressing concern you would like addressed or if you would like to lead a discussion on a research-related topic, please talk to me at the Research Roundtable or send an email to lisa.p.thompson5.civ@mail.mil.

Meanwhile, I would like to join your team to provide a 10-15 minute update on DRP services annually or every six months, before or after your program meets for didactic or lecture hall sessions. These remarks range from DRP services to upcoming events and policy updates from the Office of the Under Secretary of Defense [Personnel & Readiness and Research Regulatory Oversight Office (R202)], a review of the Minimum Education Requirements Framework (MERF), and information on required Collaborative Institutional Training Initiative (CITI) training.

Our goal is to promote research. We want to help familiarize your Graduate Medical Education (GME) trainees, faculty, and staff with DRP services to help them meet their research and scholarly project program requirements. Our services include assistance with protocol development; courses on research methods, statistics and writing; GME trainee research project funding; collaborative agreement development; manuscript editing; publication clearance and bench research space through our Biomedical Research Laboratory.

I hope to see you soon at one of our events! ⊡

Averting noncompliance pitfalls in research

Diane Beaner, research compliance officer, tackled the issue of noncompliance with a mix of reassurance and firmness at the Research Roundtable on Oct. 17.

"Noncompliance is not a bad word," Beaner said, who went on to distinguish two kinds of non-compliance: serious and continuing.

Serious noncompliance, as determined by the Institutional Review Board, heightens the risks to research subjects; adversely affects their rights, welfare or safety; or adversely impacts a study's scientific integrity. The definition also includes willful violation of policies, state and local laws, or federal regulations.

In contrast, continuing noncompliance involves a pattern of noncompliance, as gauged by the number and variety of incidents over the course of a research protocol. A full committee of the Institutional Review Board assesses the level of noncompliance for either type.

Serious noncompliance may result in a report to the Defense Health Agency or possibly the Food and Drug Administration, Beaner cautioned.

Noncompliance commonly ranges from a research team's failure to submit a study for approval renewal to use of an outdated consent form.

"Shred the old version and make copies of the new," Beaner advised for revised consent forms.

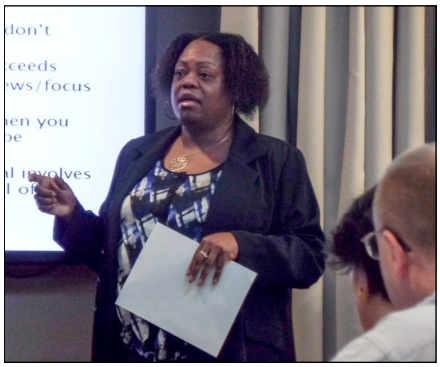
Sometimes, non-compliance can create logjams for the research team as well as for regulators, as when the team fails to report the arrival of a new principal investigator.

"If you know you're going to have a change of PI, start submitting the paperwork," Beaner said.

Finally, Beaner stressed that she and the compliance team were there to help field questions as they arise in the research process.

"I'll never say 'I don't know' with a period," Beaner said. "I'll find out for you." ⊡

To learn more about noncompliance, find slides from the talk at this link.



Diane Beaner, research compliance officer, makes a point at October's Research Roundtable. (Photo by John Fadoju)

DEPARTMENT DOWNLOAD
NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS

At an Oct. 5 staff meeting, Army Col. Peter Weina, chief of the Department of Research Programs, pointed to progress in handling research protocols.

"You're doing a phenomenal job," said Weina, citing a drop in the number of submissions awaiting action and a rise in the number of completed tasks. The last 10 approved protocols took close to the target time of 90 days, he noted.

Any research protocol begins with an official start letter from the Department of Research Programs. To help investigators launch their studies quicker, Freda Krosnick, chief of the Business Office, has compiled a one-page checklist, now online. Find it here.

For non-research inquiry, Weina stressed the importance of securing an exempt determination letter. Non-research inquiry includes quality improvement, performance improvement, evidence-based practice and Lean Six Sigma.

Hospital staff with a promising project in those areas cannot present publicly without a prior determination letter. "We can't issue retroactive determination letters," Weina cautioned.

Currently, obtaining an exempt determination letter takes about 30 days, but the department is driving toward a goal of three days. On Sept. 20, 19 staff members received training in exempt determinations, which will help to reduce the wait time for letters.

DARNALL MEDICAL LIBRARY
Research & Scholarly Communication Support

Dr. Lyubov Tmanova, DVM, MLIS, MS, informationist and biomedical research librarian, offers research support to the Walter Reed National Military Medical Center medical community and helps integrate biomedical information into medicine to advance research and scholarly communication. Dr. Tmanova offers research-centered lectures on a quarterly basis. Individual and group consultations are available upon request.

Research & Scholarly Communication Lectures

NOVEMBER 2017

Medical Genetics Resources I

Wednesday, Nov. 1, 12 p.m. · Building 1, Room 2447
Instructor: Dr. Tmanova

This lecture describes the National Center for Biotechnology Information molecular databases centered on medical genetics and genetic tests and laboratories.

Designing a Compelling Scientific Presentation

Tuesday, Nov. 21, 12 p.m. · Building 1, Room 2447
Instructor: Dr. Tmanova

This lecture will help you structure and design your research presentation using the key components and elements of scientific presentation to communicate your research findings to scientists.

To register for a class, please contact Dr. Tmanova at lyubov.tmanova.civ@mail.mil or 301-319-2475.

For a complete listing of all Darnall Medical Library classes, please see our course calendar at http://www.lrc.usuhs.edu/content/NCRClassCalendar.php?scope=Darnall&m=11&y=2017.

Faces of Research

Honoring our own

The department's own non-commissioned officer in charge, **Army Sgt. Alisha Kohler**, aced her board examination last month, winning NCO of the Quarter for Charlie Company. More informally, Army Col. Peter Weina, chief of the Department of Research Programs, lauded Kohler for finding and driving a van for department staff when a bus failed to show up at the appointed time for an off-site training event.

"Securing last-minute transportation for department personnel: That's the sign of a great NCO, making things happen when everything falls apart," added Army Col. Ann Nayback-Beebe.

Army Sgt. Alisha Kohler on the terrace of Building 17B (Photo by Paula Amann)

Jelena Gvozdenovic-Jeremic receives thanks and congratulations from Army Col. Peter Weina, chief of the Department of Research Programs, for a job well done on behalf of the Business Office, which oversees technology transfer at Walter Reed Bethesda. (Photo by John Fadoju)

In other news last month, **Jelena Gvozdenovic-Jeremic**, a technology transfer specialist with the Business Office, was recognized as part of the I Save Lives Campaign. The chief of the Department of Research Programs, Army Col. Peter Weina, praised her efforts during recent months when her team was missing a staff member.

"Most people don't know that the majority of the burden was borne by Jelena, and she continues to do an absolutely remarkable job," Weina said.

For her part, Gvozdenovic-Jeremic credited the collective work of her colleagues in the Business Office. "I really see this as a team effort," Gvozdenovic-Jeremic said.

At a prior meeting, Weina heaped special praise on **Tom Quispe**, supply management specialist, for expediting orders and managing logistics for year-end purchases.

The Department of Research Programs presents

Training for Electronic Institutional Review Board (EIRB)

Question and Answer Sessions
First and third Mondays, 1200–1300
Radiology Conference Room B015, Building 19 Basement

Month	Days
November	20
December	4
January	8 | 22

RESEARCH POLICY RESOURCES

The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked websites, or the information, products or services contained therein. For other than authorized activities such as military exchanges and Morale, Welfare and Recreation (MWR) sites, the Defense Department does not exercise any editorial control over the information you may find at these locations.

- Belmont Report
  The Belmont Report provides "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" that is found in Code of Federal Regulations, 45 CFR part 46.
- Comparison of FDA and HHS Regulations
  The FDA provides a chart comparing FDA's regulations for human subject protection with those of the Department of Health and Human Services.
- The President's Council on Bioethics
  This web site provides useful references on ethical issues that arise from advances in biotechnology and biomedical sciences.
- Clinical Trials.gov
  Clinical Trails is a service of the National Institutes of Health, provides free public access to a database of Federal and private studies taking place nationwide and provides information on clinical studies for a wide range of diseases and conditions.
- HHS Office for Human Research Protections
  HHS OHRP provides assurances and IRB registration, education, policy guidance, and workshops.
- HHS Office of Civil Rights
  HHC Office of Civil Rights provides guidance on the Health Insurance Portability and Accountability Act (HIPAA) and Standards for Privacy of Individually Identifiable Health Information *(the Privacy Rule).*
- MedlinePlus
  MedlinePlus provides medical research literature including full-text drug information and an illustrated medical encyclopedia.
- Office for Human Research Protections (OHRP)
  OHRP Guidebook (1993) provides current and historical materials about human subject protection. Caution: this serve as a guide and some information is obsolete; however, some portions remain valid.
- Federal Policy for the Protection of Human Subjects ('Common Rule')
  HHS provides information about HHS regulations, 45 CFR part 46 and four subparts a, b, c, and d.
- Protocol Review
  HHS provides guidance for protocol development, use of IRB, and Expedited Review procedures and exemptions.
- Informed Consent
- *HHS provides informed consent requirements, guidance on the use of exculpatory language, legal obligation and penalties, documentation and changes to* ***documentation.***
- Vulnerable Populations
  HHS provides guidance for populations including prisoners, children, and HIV human subjects.

FDA Regulations

- CFR – Code of Federal Regulations Title 21
- FDA Regulations Relating to Good Clinical Practice and Clinical Trials
- Preambles to GCP Regulations
- Electronic Records; Electronic Signatures (21 CFR Part 11)
- Regulatory Hearing Before the Food and Drug Administration (21 CFR Part 16)
- Protection of Human Subjects (Informed Consent) (21 CFR Part 50)
- Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products (21 CFR Parts 50 and 56)
- Informed Consent Elements (21 CFR 50.25(c))
- Exception From General Requirements for Informed Consent (21 CFR 50.23(e))
- Financial Disclosure by Clinical Investigators (21 CFR Part 54)[8]
- Institutional Review Boards (21 CFR Part 56)[9] ⊡

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The Department of Research Programs presents

2018 Research & Innovation Month

Important Dates

Call for Abstracts

- **December–January (final abstract submission deadline: 31 January)**

Staff, faculty, fellows, and trainees from all disciplines can register for a research or non-research competition by sending their abstracts and related forms in a single email to dha.bethesda.wrnmmc.mbx.researchandinnovationmonth@mail.mil.

Poster Production

- **February (poster draft submission deadline: 28 February)**

All participants must submit a poster draft to the Medical Graphic Arts Department (MGAD). Points of contact are Mary-Ann Ayrandjian (mary-ann.ayrandjian.civ@mail.mil) and Shane Stiefel (shane.m.stiefel.civ@mail.mil).

Poster Display Week

- **30 April–04 May**

All competition participants display their research posters in the Mezzanine Center, East, and West Wings of Building 9. Posters based on Unity of Effort will carry its logo in the upper right corner. Unity of Effort reflects the partnerships among Walter Reed National Military Medical Center (Walter Reed Bethesda) and its neighbors, the Uniformed Services University of the Health Sciences and the National Institutes of Health.

- **02 May – Poster Competition I (Case Reports, Evidence-Based Practice, Performance Improvement, Quality Improvement)**

Finalists from non-research competition categories present their posters to judges in Building 9, East Wing. Award ribbons will be pinned next to the winning posters of each research competition category.

- **03 May – Poster Competition II (Paul Florentino Patient and Family-Centered Care)**

Participants in this category will present their project posters for first, second, and third prizes in Building 9.

Research Symposia I and II

- **09–10 May**

Finalists for the Bailey K. Ashford and Robert A. Phillips research awards present slides on their work before judges in Main Auditorium at the National Intrepid Center for Excellence (NICoE). Winners receive certificates and medallions. Also, winners of Poster Competitions I and II will present.

6th Annual Aware for All

- **23 May**

Aware for All aims to help the public make informed decisions about clinical research participation through speakers and display tables. Research teams at Walter Reed Bethesda and groups from the National Capital Region showcase their work in the lobby of Building 19.

Spring Research Summit

- **30 May**

Research-related groups present slides, share information, and network about their work in the Main Auditorium at the National Intrepid Center for Excellence (NICoE).

For details, contact the Department of Research Programs:

dha.bethesda.wrnmmc.mbx.researchandinnovationmonth@mail.mil

RECENT PUBLICATIONS

Courtesy of Darnall Medical Library

Find articles by authors at Walter Reed Bethesda in bold.

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The Department of Research Programs presents

RESEARCH ROUNDTABLE

A forum for the research community

"How to Craft a Data-Sharing Agreement"
Sanjur Brooks, Program Manager, Human Research Protections
Department of Research Programs
Tuesday, Nov. 21, 1200–1300
Desert Conference Room 2301, Building 19 (America)

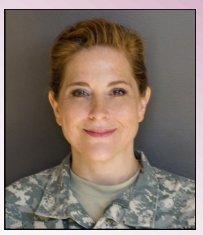
Brown bag lunches welcome.
Bring your questions on research policy!

The Department of Research Programs presents

LUNCH & LEARN: RESEARCH 2.0

A twice-monthly education series for researchers
Room 1369, Bldg. 8 (Chapel Hallway)

NOV. 8, 1200–1330
"The Many Facets of Scholarly Inquiry: A Review of Regulatory Oversight Requirements"
Col. Ann Nayback-Beebe, Deputy Chief of the Department of Research Programs



NOV. 29, 1200–1300
"Electronic Informed Consent: Ethical, Regulatory, and Practical Considerations" (Webinar by PRIM&R)
Earn credits for Minimum Education Requirements Framework (MERF) and continuing education.

Brown bag lunches welcome. Please join us!